REMARKS

Claims 1, 2 and 4-6 are pending. Claims 4 and 5 have been withdrawn from consideration.

In the final Office Action mailed May 1, 2008, claims 1, 2, and 6 have been rejected as allegedly obvious under 35 U.S.C. § 103 over U.S. Patent No. 7,087,726 to Chuntharapai et al. ("*Chuntharapai*") in view of U.S. Patent No. 5,683,712 to Cavazza ("*Cavazza*").

By this Amendment, Applicants amended claims 1 and 6, cancelled claim 2, and added new claims 7-12. Applicants respectfully request reconsideration and allowance of the pending claims in view of the amendments and remarks set forth below.

I. AMENDED CLAIM 1 IS SUPPORTED IN THE APPLICATION AS FILED

As amended, claim 1 now recites:

> 1. (Currently Amended) A medicament for ~~with immunotropic activity effective in~~ treating a disease of viral etiology comprising a homeopathically activated ~~one or more homeopathic dilutions of a potentiated~~ form of at least one monoclonal, polyclonal, or natural antibody~~ies~~ to ~~an~~ interferon~~,~~ wherein said homeopathically activated ~~the potentiated~~ form does not suppress the activity of the interferon ~~and wherein one or more homeopathic dilutions of the potentiated form of antibodies to the interferon being produced by a homeopathic potentiation technology~~.

Applicants are fully aware that the newly added limitation "homeopathically activated" is not set forth in the application in *ipsis verbis*. For this reason and to advance the prosecution on the merits, Applicants wish to address the issue preemptively and directly for Examiner's consideration.

Applicants note that *haec verbis* disclosure is not a pre-requisite for complying with the written description requirement. *See* MPEP § 2163. I. B. The description may be express, implicit, or inherent. *Id.* The key to evaluating compliance with the written description requirement is a determination whether the applicant had possession of the claimed invention based on the content of the application as a whole. *See* MPEP § 2163. II. The outcome of the evaluation depends on whether "the description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed." *See* MPEP § 2163.01, *citing In re Gostelli*,

872 F.2d 1008, 1012 (Fed. Cir. 1989).

The specification describes: a) preparation of "activated" or "potentiated" antibodies to interferon by homeopathic technology (*e.g.*, Examples 1 and 2), b) administration of the activated or potentiated form of the antibody to patients (*e.g.*, Examples 4 and 5), and c) biological effects of such administration on T-cells and phagocytes (*e.g.*, Examples 2 and 3). In combination, these disclosures clearly place "homeopathically activated form" of the antibodies to interferon in possession of the inventors as of the filing date of the above-identified application.

Therefore, Applicants respectfully submit that amended claim 1 is fully supported in the application as filed.

II. OBVIOUSNESS REJECTION OVER *CHUNTHARAPAI* IN VIEW OF *CAVAZZA*

The Examiner has rejected claims 1-2 and 6 as obvious.

Chuntharapai teaches interferon antibodies at standard concentrations. *Cavazza* teaches a transdermal patch for delivery of homeopathic drugs.

In the Office Action, the Examiner suggests that one skilled in the art would apply the homeopathic technology of *Cavazza* to the interferon antibodies of *Chuntharapai*, arriving at the medication of claim 1, which would then inherently possess the claimed properties.

Applicants strongly and respectfully disagree.

First, to set forth a *prima facie* case of obviousness, the Examiner must show that the prior art taken in its entirety provides a reason for one skilled in the art to arrive at the invention as a whole. MPEP § 2141.02. It is improper to focus on the specific difference between the prior art and the invention as such. *Id.* The question is whether the prior art in its entirety provides "an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co. v. Teleflex Inc., 127 S. Ct.* 1727, 1742 (2007).

The inventors of the present patent application discovered the homeopathically activated form of antibodies to interferon and found that it has unique properties in biological systems. Neither of the cited references motivates one skilled in the art to apply the homeopathic technology to antibodies of any kind, let alone specifically for antibodies to interferon. Nothing

in the cited art suggests the desirability of making homeopathically activated form of any antibodies (let alone for antibodies to interferon), or motivate one skilled in the art to try to do so. The Examiner appears to suggest that merely because the homeopathic technology is known, it would be obvious to apply such technology for antibodies to interferon. If this were the law, any and all homeopathic preparations of any known substance would be obvious. *Compare*, e.g., *Abbott Laboratories v. Sandoz, Inc.*, 2008 WL 4636167 (Fed. Cir., October 21, 2008) (upholding judgment of validity of claims reciting a known formulation technology for a known active ingredient and citing *KSR Int'l Co. v. Teleflex Inc.*). The Examiner is respectfully requested to note that the obviousness issue in Abbott was far closer than in the present case, where the inventors made a truly pioneering discovery of homeopathically activated form of antibodies. The fact that homeopathy and antibody preparation were known separately does not mean that the breakthrough of bringing them together is obvious. *See Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809 (1986) ("[I]n addressing the question of obviousness a judge must not pick and choose isolated elements from the prior art and combine them so as to yield the invention in question if such a combination would not have been obvious at the time of the invention."). Considering the invention as a whole, the entirety of the prior art simply did not provide an "apparent reason" to use the homeopathic technology for antibodies of interferon.

The above conclusion is not surprising, considering the unexpectedness of the properties of the claimed medication. The inventors discovered that the homeopathically activated form of antibodies to interferon both a) has a biological activity with respect to conditions of viral etiology, and b) does not suppress interferon. Nothing in the cited art suggests that antibodies treated via homeopathic technology will have a biological activity related to medical conditions of viral etiology. Even assuming, *arguendo*, that homeopathic technology is used on the antibodies in question, the prior art does not teach or suggest lack of interferon suppression. In this regard, the Examiner suggests that it would be expected that antibodies at issue would not suppress interferon because they are highly diluted. It is difficult to see, however, how one skilled in the art would expect both biological activity (efficacy) and lack of suppression. Either the preparation is so highly diluted that it has no activity and no suppression, or it has activity and then there is also a possibility of suppression of interferon. Furthermore, inherency and obviousness are entirely different legal doctrines. "Obviousness cannot be predicated on what is

unknown." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). An expectation that a claimed limitation would be inherent in the product of a combination "is not a substitute for some teaching or suggestion supporting an obviousness rejection." *Id.*

Second, to set forth a *prima facie* case of obviousness, the Examiner must show that one skilled in the art would have a reasonable expectation that the combination of *Chuntharapai* and *Cavazza* will be successful. *See* § MPEP 2143.02. Meeting the burden requires that the prior art provides some degree of predictability. *Id.*, *citing In re Rhinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). In the pharmaceutical arts, the expectation of success is reasonable when the prior art as a whole would lead one skilled in the art to believe that the claimed invention would at least have activity of some type for the stated purpose. *In re O'Farrell*, 853 F.2d 984, 903 (Fed. Cir. 1988), *In re Merck*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Moreover, the Court of Appeals for the Federal Circuit suggested that finding of reasonable expectation of success for a pharmaceutical product requires an expectation of activity greater than a baseline level of activity. *Yamanouchi Pharmaceutical, Inc. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1345 (Fed. Cir. 2000).

Applicants respectfully submit that none of the references, alone or in combination, disclose, teach or suggest anything that would lead one skilled in the art to expect that a homeopathically activated form of an antibody to interferon would have any activity, let alone the specific activity levels observed. Also, none of the cited references disclose a mechanism of action for the potentiated antibodies, or contain any other information that would suggest to an artisan that homeopathically activated antibodies to interferon would have any desired properties, let alone the specifically claimed properties. While Applicants are well aware of the decision of the United States Supreme Court in *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727 (2007), the facts of the present case do not involve a situation where "there are a finite number of identified, predictable solutions," when "a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp." *KSR Int'l* at 1742. As it is well-known to those skilled in the art, the universe of various antigen-antibody pairs is nearly limitless.

Applicants submit hereby a Declaration by Dr. Oleg Epshtein ("the *Epshtein Declaration*"). The *Epshtein Declaration* is submitted as evidence in further response to Examiner's allegations of *prima facie* obviousness. The *Epshtein Declaration* is submitted to

show absence of *prima facie* obviousness, not in rebuttal of the alleged *prima facie* case. In the *Epshtein Declaration*, Dr. Epshtein unequivocally states that one skilled in the art would not expect that a homeopathically activated form of an antibody to interferon would be active for intended purpose based on the information provided in the prior art at the time the '652 application was filed. Particularly, the *Epshtein Declaration* underscores that an artisan would not expect a combination of efficacy and lack of suppression. Applicants respectfully assert that the *Epshtein Declaration* is un-rebutted evidence of non-obviousness, and it provides further support for non-obviousness of amended claim 1. Applicants respectfully suggest the Examiner did not put forth a *prima facie* case of obviousness with respect to claim 1, as amended, and dependent claims.

On the basis of the foregoing, Applicants respectfully submit that claim 1, as amended, and dependent claims are non-obvious. Withdrawal of the rejection is respectfully requested.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-4711.

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